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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,910	10/21/2003	Athula Ekanayake	9391	3978

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THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL TECHNICAL CENTER - BOX 161
6110 CENTER HILL AVENUE
CINCINNATI, OH 45224

EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1655

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/689,910

Applicant(s)

EKANAYAKE ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 11-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/11/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-10, in the reply filed on March 8, 2006 is acknowledged. The traversal is on the ground that distinctness between the inventions has not been established. This is not found persuasive because the invention of Group I, Claims 1-10, is directed to Claims 1-10, drawn to a process for isolating theanine from a plant material comprising: a) contacting the plant material with a solvent to obtain an extract comprising theanine; b) contacting the theanine extract with an absorbent to obtain a theanine-containing eluate; and c) subjecting the theanine-containing eluate to a filtration step to obtain a theanine-rich extract, which is not co-extensive with the invention of Group II, Claims 11-19, which is drawn to a process for isolating theanine from a plant material comprising performing the following steps in order: a) contacting the plant material with a solvent to obtain an extract comprising theanine; b) microfiltering the theanine extract and retaining a theanine-containing retentate; c) contacting the theanine-containing retentate with an absorbent to obtain a theanine-containing eluate; and d) subjecting the theanine-containing eluate to a filtration step to obtain a theanine-rich extract, which is not co-extensive with the invention of Claim 20, which is drawn to a process for isolating theanine from plant material comprising a) contacting the plant material with a solvent to obtain an extract comprising theanine; b) subjecting the theanine extract to column extraction with a polyamide adsorbent to obtain a theanine-containing eluate; c) subjecting the theanine-containing eluate to ultrafiltration to obtain a theanine-rich extract; and d) further

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concentrating the theanine-rich extract. The three different methods are directed to three different processes for the isolation of theanine from a plant material comprising different process steps and different experimental parameters for the extraction of theanine. These methods are capable of separate manufacture, use or sale, as claimed, and are patentable (novel and unobvious) over each other (though they may be unpatentable because of the prior art) subjects. One would not have to practice the various methods at the same time to practice just one method alone.

Moreover, the several inventions above are independent and distinct, each from the other, and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-10 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the theanine extract" in line 4. There is a lack of clear antecedent basis for this limitation in the claim.

Claim 5 recites the limitation "the theanine eluate" in line 4. There is a lack of clear antecedent basis for this limitation in the claim.

The metes and bounds of Claim 6 are rendered uncertain by the phrase "less than about 20% ethanol" because the simultaneous use of both "less than" and "about" is inconsistent in distinctly claiming the subject matter of the instantly claimed invention. Either the solvent comprises less than 20% ethanol or about 20% ethanol. The lack of clarity renders the claim ambiguous.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al. (A*, referred herein for convenience or NN1, EP 1057483) and Ekanayake et al. (BB, US 5,879,073).

Applicant claims a process for isolating theanine from a plant material comprising: a) contacting the plant material with a solvent to obtain an extract comprising theanine; b) contacting the theanine extract with an absorbent to obtain a theanine-containing eluate; and c) subjecting the theanine-containing eluate to a filtration step to obtain a theanine-rich extract. Applicant further claims the process of claim 1, wherein the plant material comprises tea leaves. Applicant further claims the process of claim 2, wherein the solvent is selected from the group consisting of water, ethanol, and mixtures thereof. Applicant further claims the process of claim 3, wherein the adsorbent is a polymeric resin. Applicant further claims the process of claim 1, wherein step b) is performed using column extraction. Applicant further claims the process of claim 9, wherein the theanine-rich extract of step c) is further concentrated.

At [0052], Ueda teaches, "Ten kilograms of tea leaves (*Camellia sinensis* L.) were extracted with boiling water. The resulting extract was applied to a cation exchange resin ("Dowex HCR W-2," manufactured by Muromachi Kagaku Kogyo K. K.), and eluted with 1 N NaOH. The eluted fraction was applied to an activated carbon ("Taiko Kasseitan SG" manufactured by Futamura Kagaku Kogyo K. K.), and eluted with 15% EtOH, to give an eluted fraction. The resulting eluted fraction was concentrated using an RO membrane (Nitto Denko "NTR 729 HF"), and then purified by column chromatography, to give a purified product. Furthermore, the purified product was recrystallized, to give 24.8 g of L-theanine."

Ekanayake teaches a process for isolating a theanine comprising from tea leaves comprising: a) extracting green tea at an elevated temperature with an aqueous solution (with or without acid) to obtain an extract comprising theanine, in Column 4, line 36 to Column 6, line 18. Ekanayake teaches extracting the green tea plant material with an aqueous acid solution removes some metal ions, such as iron, and some of the oxidized phenolic components, such as theaflavins, thearubigins and quinines, in Column 4, lines 54-61. See Column 6, lines 1-18, wherein Ekanayake teaches green tea extracts obtained by acid extraction contain theanine; b) treating the theanine-containing extract with a cation exchange polymeric resin in a container to remove metal ions and to improve clarity and taste of the resultant product to obtain a theanine-containing eluate, in Column 6, line 19 to Column 7, line 63. In Column 6, lines 53-62, Ekanayake teaches that the green tea extract can be treated with the adsorbent material by any conventional method that results in an intimate contact of the resin and the extract, such

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as methods encompassing the use of fluidized beds, stirred tanks, batch tanks, and concurrent and countercurrent flow columns. See Column 15 to Column 17, line 34; and c) subjecting the theanine-containing eluate to a filtration step to obtain a theanine-rich extract, in Column 7, line 65 to Column 10, line 3. Ekanayake teaches subjecting the cation exchange resin treated extract to a filtering step removes high molecular weight materials such as pectins, proteins, chlorophylls, thearubigins, theaflavins, and oxidation products, in Column 7, line 64 to Column 8, line 6. In Column 10, lines 4-17, Ekanayake teaches that the treated, filtered green tea extract can be further concentrated. In Column 10, line 41-47, Ekanayake teaches that the green tea extracts prepared by the referenced method are enriched in theanine.

The references anticipate the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekanayake et al. (BB, US 5,879,073) in view of Bailey et al. (B*).

Applicant's claimed invention of Claims 1-4 and 10 was set forth above.

Applicant further claims the process of claim 1, wherein in step b), the contacting comprises: i) adding the adsorbent to the theanine extract in a container, ii) mixing the

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adsorbent and the theanine extract; and iii) separating the theanine eluate from the adsorbent.

The teachings of Ekanayake were set forth above. Ekanayake teaches the instantly claimed invention except for wherein in step b), the contacting comprises: i) adding the adsorbent to the theanine extract in a container, ii) mixing the adsorbent and the theanine extract; and iii) separating the theanine eluate from the adsorbent.

However, it would have been obvious to one of ordinary skill in the art to replace the process step for treatment of the theanine-containing green tea extract with a polymeric resin using column extraction taught by the process for isolating theanine from green tea leaves taught by Ekanayake by contacting the theanine-containing green tea extract with the instantly claim-designated process steps and experimental parameters, as recited in Claim 5, to provide the instantly claimed invention because at the time the invention was made it was known in the art that the instantly claimed process steps, ingredient and experimental parameters were useful in the extraction of desirable components from green tea extracts, as evidenced by the teachings of Bailey. For instance, in Column 2, lines 38-44, Bailey teaches, "As the cation exchange treatment of tea extract, it is possible to choose between a column method of letting the extract flow through a filled column with the cation exchange resin bonding to potassium ion and a batch method in which the extract is contacted to the resin in a tank or the like."

At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to replace the process step for treatment of the theanine-containing green tea extract with a polymeric

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resin using column extraction taught by the process for isolating theanine from green tea leaves taught by Ekanayake by contacting the theanine-containing green tea extract with the instantly claim-designated process steps and experimental parameters, as recited in Claim 5, to provide the instantly claimed invention because Bailey suggests that cation exchange treatment of tea extract for the isolation of desirable tea components can be affected by either a column method wherein a column is filled with a polymeric resin or by a batch method by contacting the green tea extract to resin contained in a container; and, like Bailey, Ekayanake also teaches that green tea extract can be treated with the adsorbent material by any conventional method that results in an intimate contact of the resin and the extract, such as methods encompassing the use of fluidized beds, stirred tanks, batch tanks, and concurrent and countercurrent flow columns, in Column 6, lines 53-62. Thus, the claim-designated limitations would have been no more than a matter of judicious selection to one of ordinary skill in the art or the skilled artisan practicing the invention at the time the invention was made to pick and choose the experimental parameters for contacting a green tea extract with an adsorbent material to provide a method of isolating theanine from a green tea extract because at the time the invention was made the prior art taught that such process steps, ingredients and experimental parameters were conventional in methods of treating green tea extracts with a cation exchange resin to provide a result-effect variable in the isolation of theanine from green tea.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekanayake et al. (BB, US 5,879,073) and Bailey et al. (B*) in view of Zhongyu et al. (U) and Burdick et al. (PP, EP 1077211).

Applicant further claims the method of claim 7, wherein the adsorbent is a polyamide. Applicant's claimed invention of Claims 1-7 and 10 was set forth above. Applicant further claims the process of claim 7, wherein the adsorbent is a polyamide.

The combined teachings of Ekanayake and Bailey were set forth above. The combined teachings of Ekanayake and Bailey teach the instantly claimed invention except for wherein the adsorbent is a polyamide. However, it would have been obvious to one of ordinary skill in the art to replace the adsorbent used in the method of isolating theanine taught by the combined teachings of Ekanayake and Bailey because at the time the invention was made it was known in the art that polyamide as an adsorbent was useful in the isolation or separation of theanine and polphenolic compounds, as evidenced by the teachings of Zhongyu and Burdick. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to replace the adsorbent used in the method of isolating theanine taught by the combined teachings of Ekanayake and Bailey to provide the instantly claimed method because Zhongyu taught that while polyamide

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extract tea polyphenols, "Substances like amino acids (theanine) were not adsorbed by PA/SiO₂ and thus easily separated"; like Zhongyu, Burdick taught that polyamide adsorbents are useful in extracting tea polyphenols, such as the catechins, epicatechin and epigallocatechin gallate contained in the theanine-rich tea extract obtained in the method taught by the combined teachings of Ekanayake and Bailey; like, both Zhongyu and Burdick, Bailey taught that separation of catechins from crude tea extracts can be affected by the use of a polyamide as an adsorbent material to recover essentially caffeine free catechins, wherein extraneous materials having little affinity for polyamide are washed off the adsorbent material with water or an aqueous ethanol mixture (10% ethanol), in Column 5, line 20 to Column 6, line 15.

As each of the references indicate that the various ingredients, process steps and experimental parameters used in the process of producing the claimed extract are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by each of the references.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
May 15, 2006